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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,526	06/16/2000	Richard M. Lawn	99.395-A	9969

7590 05/07/2002

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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/595,526	LAWN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Manjunath N Rao	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to polypeptide with SEQ ID NO:2, classified in class 530, subclass 350.
- II. Claims 3-24, 33-34, drawn to polynucleotide with SEQ ID NO:1, vectors, host cells, method of making a protein, classified in class 435, subclass 69.1.
- III. Claim 25, drawn to polypeptide with SEQ ID NO:8, classified in class 530, subclass 350.
- IV. Claims 26-27, 31, drawn to polynucleotide with SEQ ID NO:7 and vector, classified in class 435, subclass 320.1.
- V. Claim 28, drawn to a polypeptide with SEQ ID NO:10, classified in class 530, subclass 350.
- VI. Claims 29-30 and 32, drawn to polynucleotide with SEQ ID NO:10 and vector, classified in class 435, subclass 320.1.
- VII. Claims 35-45, drawn to a method of increasing cholesterol efflux by administering expression vectors comprising ABC1, classified in class 514, subclass 44.
- VIII. Claim 46-53, drawn to a method of increasing cholesterol efflux by administering a compound that increases expression of ABC1, classified in class 514, subclass 789.

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- IX. Claim 54, drawn to a method of increasing cholesterol efflux by administering a compound that increases ABC1 activity, classified in class 514, subclass 789.
- X. Claims 55-61, drawn to a method for screening a compound that promotes ABC1-mediated cholesterol efflux, classified in class 435, subclass 11.
- XI. Claims 62-64, drawn to a method of detecting the comparative level of ABC1 expression, classified in class 435, subclass 6.
- XII. Claims 65-69, drawn to a method for detecting ABC1 protein levels, classified in class 436, subclass 86.
- XIII. Claims 70-74, drawn to antibody and a kit, classified in class 530, subclass 387.1.
- XIV. Claims 75-76, drawn to a kit comprising an antisense ABC1 oligonucleotide, classified in class 536, subclass 24.5

The inventions are distinct, each from the other because of the following reasons:

Inventions I through VI, XIII, XIV are patentably distinct from each other. The polypeptide of group I, III, V and the polynucleotide of group II, IV, VI, and XIV, the antibody of group XIII, each comprise amino acid sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions I, III, V and VII, VIII, IX, X, XI, are patentably distinct from each other. The polypeptides of group I, III and V are products which are neither used nor made in the methods

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of groups VII, VIII, IX, X, XI. They have separate utilities, and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions I, III, V and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used for making specific antibodies as opposed to its use a standard in determining the levels in mammalian cells.

Inventions II, IV, VI, XIV and inventions VII, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be used for making recombinant proteins as opposed to its use in the methods of groups VII and XI.

Inventions VII-XII are patentably distinct from each other. The method of increasing cholesterol efflux using expression vectors of group VII, the method of increasing cholesterol efflux using a compound that increases expression of ABC1 of group VIII, a method of increasing cholesterol efflux by administering a compound that increases ABC1 activity of group IX, a method of screening a compound that promotes ABC1-mediated cholesterol efflux

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of group X, a method for detecting the comparative level of ABC1 expression of group XI, a method of detecting ABC1 protein levels of group XII are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Galina Yakoleva on 4-18-02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Manjunath N. Rao. Ph.D.

April 26, 2002